PlastiBell® Circumcision Device
Instructions for Use

MABIS HEALTHCARE

(US) Using the PlastiBell® Circumcision Device

Caution: The glans must be free in its entirety under the device. Pressure is caused by 1) pulling the foreskin too far forward in an attempt to remove maximum tissue, or 2) using a device that is too small.

Using a device that is too large and/or pulling the foreskin too far forward may cause the bell to slip over the glans onto the penile shaft. Edema may result and contribute to damage to the skin and underlying tissue. It would then be necessary to cut off the ring using a standard guide and finger-ring cutter.

The ligature must be tied securely with surgeon's knot.

The parents should be instructed to call the physician if the bell has not fallen off within eight days, or immediately if it has migrated onto the penile shaft from its original position or if the penis becomes edematous. (Information leaflets provided should be given to parents to supplement the physician's instructions.)

How to Use the PlastiBell® Circumcision Device

1. After applying two hemostats to foreskin, gently separate the adhesions using either the pointed or spatula end of the probe.
2. Use two hemostats to spread the foreskin and another to crush the foreskin where the dorsal slit is to be made. The foreskin should be crushed to a length that is approximately the same as the width of the glans. This can be visualized while the foreskin is being pulled and dissected. Place ligature with surgeon's knot and leave loose at the base of the penis.
3. With tissue scissors, make the dorsal slit along the crushed line. The slit should be no longer than necessary to permit the bell to be worked into place, and it should not exceed the length of the previously crushed area. Gently retract the foreskin and free any remaining adhesions, completely exposing sulcus.
4. Place bell of appropriate size (see "Proper Size Selection") over the glans so it avoids undue pressure on ventral vessels. Too small a bell may injure the glans. Too large a bell may eventually slip over the corona and onto the shaft, possibly causing edema and damage to skin and underlying tissue. Apex of dorsal slit should be distal to bell's groove. Pull foreskin only enough to position apex of dorsal slit distal to groove. If excessively pulled, it may later draw the bell too tightly against or over the glans onto the shaft. There should be approximately 1.0 cm between the sulcus and the groove of the bell where the ligature will be applied.

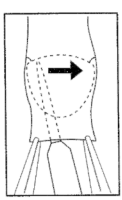
4a. These two suggestions may prove of additional value:
- To hold bell while tying ligature, the third hemostat may be used to clamp foreskin to handle, as illustrated.
- If slit is too long, cross the two hemostats over each other to hold the bell in place.

5. After positioning ligature around bell's groove, draw ligature very tightly so it compresses foreskin into groove; tie with surgeon's knot. Snip off excess ligature. You should be able to see an unobstructed urethral meatus. Trim off foreskin using outer ridge of bell as cutting guide. Maintain adequate traction on the fore skin and trim as much tissue as possible to reduce the amount of remaining necrotic tissue. If ligature is not tightly secured, oozing will occur and the bell may fall off, or the line of excision will be incomplete, thereby requiring subsequent removal of tissue tags.
6. Break off bell handle and discard it. Leaving the bell and ligature in place, you should be able to see an unobstructed urethral meatus. No dressing is necessary. The rim of tissue under and distal to the ligature will become necrotic and separate with the bell in 5 to 8 days, leaving a clean, healed line of excision. If the physician desires, the bell can be removed before the infant is sent home by cutting the ligature at the knot. This may be done after 36 to 48 hours following circumcision, based on physician's evaluation.

Proper Size Selection

Proper size selection is most important since the PlastiBell device may remain in place for as long as five to eight days. After the foreskin has been retracted (see Step 3), the proper bell size can easily be determined.
Too Small: PlastiBell device is too small. Ring exerts undue pressure on the sides of the glans. Use of a bell this size may cause local necrotic changes and periurethral edema to the point of causing urinary retention. May also result in insufficient circumcision.
Too Large: PlastiBell device is too large and the entire glans slips through too easily. Use of a bell this size may cause overstretching of the foreskin and increase the possibility of edema. Excessive tension created may cause ring to slide onto shaft of penis. Too much foreskin may be removed using bell this size.
Proper Size: PlastiBell device is of proper size to "cap" the glans. Base of bell may reach sulcus without exerting pressure on the sides of the glans. Corona of glans does not slip through the top of the bell. Do not pull foreskin too far forward creating undue pressure. Ligation at the bell's groove will remove the proper amount of foreskin.

WARNING: To help reduce the potential for infection and/or other complications, do not re-use.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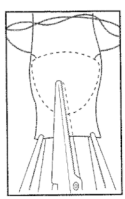
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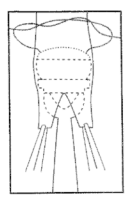
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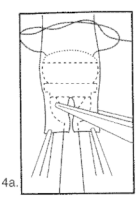
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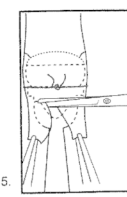
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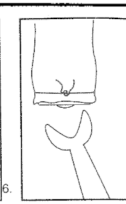

MABIS HEALTHCARE

Now that your baby has been circumcised...

Nyní, když byla Vašemu dítěti provedena obřízka...

Nu, hvor din baby er blevet omskåret...

Nu uw baby een circumcisie heeft ondergaan...

Nyt kun vauva on ympärileikattu...

Maintenant que votre bébé a été circoncis...

Nun ist bei Ihrem Baby die Beschneidung durchgeführt worden...

Gyermeke átesett a körülmetélésen...

Ora che il vostro bambino è stato circonciso...

Dabar, kai jūsų kūdikis buvo apipjaustytas...

Tagad jūsu bērniņš ir apgraizīts...

Kiedy Twoje dziecko zostało już obrzezane....

Agora que o seu bebé foi circuncisado...

Agora que o seu bebé foi circuncidado....

Теперь вашему ребенку сделали обрезание...

Ahora que su bebé ha sido circuncidado....

Nu när din baby har omskurits....

Rx Only CE 0086

MABIS HEALTHCARE

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PlastiBell® Circumcision Device

1. The plastic ring usually drops off five to eight days after circumcision. No special dressing is required, and the baby can be bathed and diapered as if he had not been circumcised.

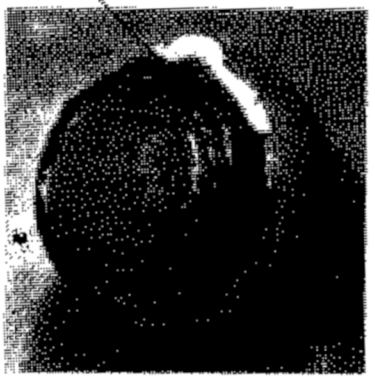
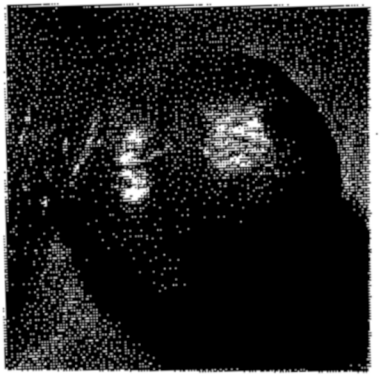
Note: A dark brown or black area around the plastic ring is natural. This will disappear when the ring drops off.

2. The result is a clean, well-healed line of excision.

Be sure to notify your doctor immediately if any of the following occur:

- unusual swelling
- the plastic ring has not fallen off within eight days
- the ring has slipped onto the shaft of the penis
- healing does not proceed as described by the Healthcare Provider.

PlastiBell Ring



Ligature